IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

DALE AARON, Personal Representative of the Estate of Randy Aaron,	)	
Plaintiff,	)	
v.	)	2:07cv927
	)	**Electronic Filing**
WYETH,	)	
Defendant.	)	

MEMORANDUM OPINION

February 19, 2010

I. INTRODUCTION

Dale Aaron, Plaintiff and Personal Representative of the Estate of Randy Aaron ("Plaintiff" or "D. Aaron"), filed a five (5) count complaint against Defendant Wyeth alleging causes of action under theories of: (1) strict liability[1]; (2) negligence; (3) breach of warranty; (4) wrongful death; as well as (5) a cause of action under the Pennsylvania Survival Statute, 42 PA. CONS. STAT. ANN. § 8302. Wyeth has filed a motion for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure, and in support of its motion filed a memorandum of law and a concise statement of undisputed material facts. Plaintiff has responded and the motion is now before the Court.

The Local Rules of the United States District Court for the Western District of Pennsylvania require that Plaintiff file responsive "concise statement which responds to each numbered paragraph in the moving party's Concise Statement." *See* LR 56.1(C)(1). Material facts set forth in a moving party's concise statement of material facts will be deemed admitted for the purpose of deciding the motion for summary judgment "unless specifically denied or otherwise controverted by a separate concise statement of the opposing party." *See* LR 56.1(E).

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[1] On November 16, 2007, this Court entered an Order granting Wyeth's motion for partial judgment on the pleadings, Plaintiff having consented, and entered judgment in favor of Wyeth on Plaintiff's strict liability claims.

Plaintiff has failed to file a response to Wyeth's concise statement of undisputed material facts. The material facts set forth in Wyeth's concise statement of undisputed material facts, therefore, are deemed admitted for the purpose of this motion for summary judgment.

II. STATEMENT OF THE CASE

In the summer of 2005, Randy Aaron ("Aaron"), thirty-six (36) years of age, began exhibiting signs of depression. Wyeth Concise Statement of Undisputed Facts ("Wyeth CSUF") ¶¶ 5, 6 & 7. Aaron's supervisor at the Pennsylvania Department of Transportation suggested that he seek help through the Commonwealth's employee assistance program. Wyeth CSUF ¶ 8. Aaron took advantage of the Commonwealth's program and made an appointment to see Joseph Perry, Ph.D., a licensed counseling psychologist. Wyeth CSUF ¶ 9.

During his appointment on July 27, 2005, Aaron told Dr. Perry, *inter alia*, that: (1) he had suffered from anxiety for several years; (2) more recently, he had been feeling depressed on a daily basis; (3) he believed his employer was "bugging" his home; and (4) three to four days per week, he would consume six to seven beers at a sitting. Wyeth CSUF ¶¶ 9, 10 & 11. Dr. Perry diagnosed Aaron as suffering from major Depressive Disorder, Generalized Anxiety Disorder, Panic Disorder and Delusional Disorder, and gauged Aaron's mental illness as "moderate to severe." Wyeth CSUF ¶ 12. Though Dr. Perry planned to continue counseling Aaron, he recommended that Aaron consider hospitalization and an evaluation by either a psychiatrist or another medical doctor for antidepressant treatment. Wyeth CSUF ¶ 13. Aaron decided against hospitalization, but indicated to Dr. Perry that he would consider seeing a psychiatrist. Wyeth CSUF ¶ 14.

Dr. Perry also discussed the possible occurrence of suicidal thoughts with Aaron, and instructed him to either call Dr. Perry or go to the nearest hospital if Aaron should have such thoughts. *Id.* On that same day, Dr. Perry called Aaron's primary care physician's office, spoke with a nurse and recommended that Aaron be evaluated for antidepressant treatment. Wyeth

CSUF ¶ 15. Although he was not Aaron's regular physician, the nurse informed Jason Rasefske, M.D. ("Dr. Rasefske") that Dr. Perry called and had recommended that Aaron be evaluated for the appropriateness of an antidepressant prescription. Wyeth CSUF ¶ 16.

Dr. Rasefske reviewed Aaron's chart, which indicated Aaron had no prior mental health treatment, and without speaking with either Aaron's regular physician or with Dr. Perry, prescribed thirty 75 mg. Effexor XR capsules for Aaron. Wyeth CSUF ¶¶ 16 & 17. The nurse called the prescription in to a local pharmacy and it was filled on July 27, 2005. Wyeth CSUF ¶¶ 18 & 27.

On August 3, 2005, Aaron met with Dr. Perry and informed him that since his last visit he had quit his job, had stop taking his medication, and had resumed the medication that morning. Wyeth CSUF ¶ 28. Aaron refused Dr. Perry's suggestion that he consider hospitalization, but agreed to allow Dr. Perry to set an appointment for him with a psychiatrist. *Id.* Aaron met with Dr. Perry again on August 5, 2005, and reported that: he did not want to take his medication; he would not consider hospitalization; and he would keep his appointment with a psychiatrist scheduled for August 8, 2005. Wyeth CSUF ¶ 29. Aaron denied having had any suicidal thoughts or plans. Wyeth CSUF ¶ 30. On August 7, 2005, Aaron died in his home due to a self-inflicted gunshot wound to the head. Wyeth CSUF ¶ 31.

Plaintiff alleges that it was not Aaron's mental illness, but rather the inadequate warnings on his antidepressant medication that caused him to commit suicide. Plaintiff herein is asserting claims of negligent failure to warn, negligent design, and breach of express warranty against Wyeth, Effexor's manufacturer.

III. LEGAL STANDARD FOR SUMMARY JUDGMENT

Pursuant to FED. R. CIV. P 56(c), summary judgment shall be granted when there are no genuine issues of material fact in dispute and the movant is entitled to judgment as a matter of law. To support denial of summary judgment, an issue of fact in dispute must be both genuine

and material, *i.e.*, one upon which a reasonable fact finder could base a verdict for the non-moving party and one which is essential to establishing the claim. *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986). When considering a motion for summary judgment, the court is not permitted to weigh the evidence or to make credibility determinations, but is limited to deciding whether there are any disputed issues and, if there are, whether they are both genuine and material. *Id*. The court's consideration of the facts must be in the light most favorable to the party opposing summary judgment and all reasonable inferences from the facts must be drawn in favor of that party as well. *Whiteland Woods, L.P. v. Township of West Whiteland,* 193 F.3d 177, 180 (3d Cir. 1999), *Tigg Corp. v. Dow Corning Corp.*, 822 F.2d 358, 361 (3d Cir. 1987).

When the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In the language of the Rule, the nonmoving party must come forward with "specific facts showing that there is a genuine issue for trial." FED. R. CIV. P 56(e). Further, the nonmoving party cannot rely on unsupported assertions, conclusory allegations, or mere suspicions in attempting to survive a summary judgment motion. *Williams v. Borough of W. Chester*, 891 F.2d 458, 460 (3d Cir.1989) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)). The non-moving party must respond "by pointing to sufficient cognizable evidence to create material issues of fact concerning every element as to which the non-moving party will bear the burden of proof at trial." *Simpson v. Kay Jewelers, Div. Of Sterling, Inc.*, 142 F. 3d 639, 643 n. 3 (3d Cir. 1998), *quoting Fuentes v. Perskie*, 32 F.3d 759, 762 n.1 (3d Cir. 1994). Moreover, the non-moving party cannot defeat a well supported motion for summary judgment by simply reasserting unsupported factual allegations contained in his pleadings. *Williams v. Borough of West Chester*, 891 F.2d 458, 460 (3d Cir. 1989).

IV. DISCUSSION

A. Preemption and Plaintiff's Negligent Failure-to-Warn Claim

Wyeth argues that the Food and Drug Administration's (FDA's) drug labeling determinations and/or requirements preempts Plaintiff's state negligent failure-to-warn claim. Federal "preemption is an affirmative defense on which [the] defendant bears the burden of proof." *Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co. KG*, 510 F.3d 77, 102 (1st Cir. 2007), *cert. denied*, 129 S. Ct. 58, 172 L. Ed. 2d 25 (2008); *see also Wyeth v. Levine*, 129 S. Ct. 1187, 1193 (2009)(characterizing a manufacturer's argument that federal drug law pre-empted the plaintiff's claims as a defense).

The Supreme Court has recognized that federal preemption comes in three forms. The first is explicit preemption which occurs when a federal enactment expressly preempts state law. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001); *English v. General Electric Co.*, 496 U.S. 72, 78 (1990)("Congress can define explicitly the extent to which its enactments pre-empt state law."). The second is implied conflict preemption which arises when state law conflicts with a federal statute. *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 239 (3d Cir. Pa. 2009). Implied conflict preemption can arise in one of two situations; (1) when it is "impossible for a private party to comply with both state and federal requirements" *id.* (quoting *English v. General Elec. Co.*, 496 U.S. at 78-79); or (2) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). Finally, implied field preemption can "be inferred from a scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, or where an Act of Congress 'touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *English v. General Elec. Co.*, 496 U.S. at 79 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

In every preemption case, however, "the purpose of Congress is the ultimate touchstone .

. ." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). A court must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 129 S. Ct. at 1194-1195 (citations omitted). "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." *Bates v. Dow AgroSciences*, 544 U.S. 431, 449 (2005). When faced with two equally plausible readings of statutory text, the court has "a duty to accept the reading that disfavors preemption." *Id.*; *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). Therefore, this Court must evaluate Wyeth's preemption arguments in light of the assumption "that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Wyeth v. Levine*, 129 S. Ct. at 1195 n. 3 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. at 485).

Wyeth argues that it is entitled to summary judgment on Plaintiff's state law failure-to-warn claim because federal law, in the form of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et. seq.*, preempts the state law claim. Specifically, Wyeth contends that the FDA has historically regulated the suicide related warnings for Effexor and other modern antidepressants reflecting extensive, ongoing and careful FDA oversight and control. Further, Wyeth argues that clear evidence exists in this instance that the FDA: (1) drafted its own warnings; (2) required the entire class of modern antidepressants to carry these warnings; and (3) repeatedly rejected efforts to implement different or additional warnings. Therefore, Wyeth contends that it would have been impossible to simultaneously comply with both state-law duties required by tort claims and with federal labeling laws.

In *Wyeth v. Levine*, the Supreme Court recently addressed the issue of "whether the FDA's drug labeling judgments preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." *Wyeth v. Levine* 129 S. Ct. at 1193. In *Levine*, the plaintiff brought state law claims against the defendant drug manufacturer alleging that the company failed to provide an adequate warning about the

risks of administering a particular drug, Phenergan, through an "IV push" method after plaintiff developed gangrene that required amputation of her forearm. *Id.* at 1189. The defendant argued that the plaintiff's state law failure-to-warn claims were preempted because the manufacturer could not simultaneously comply with both state-law duties required by tort claims and federal labeling duties. *Id.* The drug manufacturer also argued that requiring it to comply with state law duties to provide stronger warnings would interfere with Congress' purpose of entrusting an expert agency with drug labeling decisions. *Id.* at 1190.

In holding that the FDA's approval of Wyeth's label did not provide a complete defense to the plaintiff's failure to warn claim under a federal preemption theory, the Court emphasized that it was Congress' intent that state law act as a "complimentary form of drug regulation" because "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id.* at 1202. The Court further emphasized:

> State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the [Federal Food, Drug and Cosmetic Act's] premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Id. Moreover, the Court found no Congressional intent to vest the FDA with the sole authority to ensure drug safety and effectiveness, as would result from the preemption of state tort actions. *Id.* at 1200.

Levine, however, does not render state law failure-to-warn claims immune to preemption in every case. The Supreme Court recognized that "some state-law claims might well frustrate the achievement of congressional objectives" in the federal regulation of drug labeling. *Wyeth v. Levine*, 129 S. Ct. at 1204. To prevail here, Wyeth "faces an exacting burden to establish preemption of state law claims because compliance with both state and federal requirements for drug labeling is not impossible 'absent clear evidence that the FDA would not have approved a

change' in the drug's labeling." *Forst v. Smithkline Beecham Corp.*, 639 F. Supp. 2d 948, 953-954 (E.D. Wis. 2009)(quoting *Wyeth v. Levine*, 129 S. Ct. at 1198).

In *Forst v. Smithkline Beecham Corp.*, a case very similar to the instance action, Plaintiffs brought a products liability and personal injury action against Defendant Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), the manufacturer of the drug Paxil CR® ("Paxil"), after an attempted suicide by one of the plaintiffs after shortly after beginning use of Paxil. *Forst v. Smithkline Beecham Corp.*, 639 F. Supp. 2d at 950. The District Court denied GSK's motion for summary judgment based upon federal preemption of the state law claims after applying *Levine* and addressing the same arguments set forth here by Wyeth. This Court agrees that the Supreme Court's decision in *Levine* compels the denial of Wyeth's summary judgment motion based upon federal preemption.

Wyeth argues that preemption applies because the FDA repeatedly rejected efforts to implement different or additional warnings raising a direct conflict between its duties under state law and federal labeling requirements. The Supreme Court specifically found that a drug manufacturer "bears responsibility for the content of its label at all times." *Wyeth v. Levine*, 129 S. Ct. at 1197. Wyeth's contention that it would have violated federal law regarding misbranding if it had enhanced its warning without FDA approval is without merit. A drug is not misbranded under the FDCA simply because a drug manufacturer modifies a previously-approved label by including enhanced warnings. *Id.* Specifically, the Court stated:

> The FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label; instead, the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include "adequate warnings." 21 U.S.C. § 352(f). Moreover, because the statute contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a drug is misbranded is not conclusive. *See* [21 U.S.C.] §§ 331, 332, 334(a)-(b). And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning . . . is difficult to accept

Wyeth v. Levine, 129 S. Ct. at 1197. State law failure-to-warn claims, therefore, do not directly

conflict with FDA-mandated labeling.

Wyeth also argues that it was impossible for it to provide the warnings Plaintiff contends were required and also comply with federal law. Wyeth contends that Plaintiff has failed to identify any "newly acquired information" that would have allowed it to provide additional warnings under the "change being effected"("CBE") regulation, 21 C.F.R. § 314.70(c)(6)(iii). Moreover, Wyeth asserts that it has shown clear evidence of impossibility in that the FDA: (1) drafted its own warnings; (2) required the entire class of modern antidepressants to carry these warnings; and (3) repeatedly rejected efforts to implement different or additional warnings. Impossibility preemption, however, is a "demanding defense," *id.* at 1199, and this Court is unable to find that it would have been impossible for Wyeth to place a warning on its Effexor other than the warnings in place at the time the antidepressant was prescribed for Aaron. Though the FDA disagreed with certain changes to the Effexor labeling proposed by Wyeth, Wyeth did not press its position, it instead acquiesced to the requests made by the FDA. Moreover, Wyeth agreed to revise its product labeling to incorporate the class labeling for all selective serotonin reuptake inhibitors ("SSRIs"). Such evidence does not definitively show that it was impossible for Wyeth to enhance its safety warnings in place at the time of Aaron's suicide. Accordingly, Pennsylvania tort law is not preempted by federal drug labeling laws.

B. Failure-to-Warn - The Learned Intermediary Doctrine

Under Pennsylvania law[2], strict liability is imposed on the manufacturer or seller of a product in a defective condition unreasonably dangerous to the user or consumer. *Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971). A product may be deemed defective if it lacks "adequate warnings or instructions necessary for safe use of the product." *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa. Super. 1996)(quoting *Fletcher v. Raymond Corp.*, 623 A.2d

[2] Federal courts sitting in diversity must apply the substantive law of the forum state. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938). There is no dispute in this instance that Pennsylvania law controls Plaintiff's claims.

845, 848 (Pa. Super. 1993)). With regard to defective products, Pennsylvania has adopted the Restatement (Second) of Torts § 402A(1), which imposes strict liability upon sellers of unreasonably dangerous products. RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965). Comment k to § 402A, however, provides:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

RESTATEMENT (SECOND) OF TORTS, § 402A, Comment k. Pennsylvania courts have made clear that prescription drugs are "unavoidably unsafe products" within the meaning of comment k, and therefore, strict liability will not be imposed against manufacturers in suits for injuries relating to the use of prescription drugs. *See Hahn v. Richter*, 673 A.2d 888, 889-890 (Pa. 1996).

In *Hahn v. Richter*, a failure to warn lawsuit against a prescription drug manufacturer, the Pennsylvania Supreme Court explicitly stated that "[s]ince the strict liability rule of § 402A is not applicable, the standard of care required is that set forth in § 388 of the Restatement . . . . Under this section, the supplier has a duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Hahn v. Richter*, 673 A.2d at 890. Relying on long line of Pennsylvania cases, the Court held that where the adequacy of the warning accompanying prescription drugs is at issue, negligence is the sole avenue of recovery. *Id.*; *see also Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1353-55 (3d Cir. 1992); *Baldino v. Castagna*, 478 A.2d 807 (Pa. 1984); *Incollingo v. Ewing*, 282 A.2d at 220 n. 8. Since *Hahn*, then, courts applying Pennsylvania law, have consistently held that negligence is the only theory upon which a prescription drug manufacturer can be held liable for failure to warn. *See Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006); *Lineberger v. Wyeth*, 894 A.2d 141, 145 (Pa. Super. 2006); *Kline v. Pfizer, Inc.*, 2008 U.S. Dist. LEXIS 101655, 6-7 (E.D. Pa. Oct. 31, 2008). Therefore, the only cognizable claims Plaintiff has against Wyeth, as a manufacturer of prescription drugs, are negligence claims based upon (1) manufacturing defect or (2) failure to

warn.

Under Pennsylvania law the determination whether a warning is adequate is a question of law. *Mackowick v. Westinghouse Elec. Corp.*, 575 A.2d 100, 102 (Pa. 1990); *Mazur v. Merck & Co.*, 964 F.2d at 1366. The Pennsylvania Supreme Court has consistently formulated the prescription drug manufacturer's duty to warn under the § 388 "reasonableness" standard. *Id.* at 1354. It is also well-settled under Pennsylvania's "learned intermediary doctrine," that the duty of a drug manufacturer to warn of the possible dangers and side effects of prescription drugs runs to the physician, and not to the patient or to the general public. *Baldino v. Castagna*, 478 A.2d at 812; *Lineberger v. Wyeth*, 894 A.2d at 149-150; *Mazur v. Merck & Co.*, 964 F.2d at 1355. A prescription drug manufacturer has "'a duty to exercise reasonable care to inform those for whose use the article [was] supplied of the facts which make [the product] likely to be dangerous . . . .' However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer." *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa. Super. 1987)(quoting *Incollingo v. Ewing*, 282 A.2d at 220 n. 8). The adequacy of warnings is determined on the basis of the information that was known or knowable at the time the cause of action accrued. *Mazur v. Merck & Co.*, 964 F.2d at 1366; *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 458 (Pa. Super. 1973). Further, warnings that meet federal drug labeling requirements are afforded some deference. *Mazur v. Merck & Co.*, 964 F.2d at 1366.

The physician, acting as the "learned intermediary" between the manufacturer and consumer, has a duty to use the information obtained from the manufacturer, as well as his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of the patient, to determine whether to prescribe a given drug. *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. 1990), *appeal denied*, 527 Pa. 603, 589 A.2d 693 (Pa. 1991)(quoting *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523

A.2d at 378 ; *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 457 (Pa. Super. 1973). It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. *Taurino v. Ellen*, 579 A.2d at 927; *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d at 378.

In discussing the rationale behind the "learned intermediary" doctrine, the Pennsylvania Superior Court explained:

> In approving a drug for marketing purposes, the [FDA] is ever mindful of risks inherent in the use of a proposed drug. It also approves same because of the benefit said drug may have for the public as a whole. Every surgical procedure carries certain risks, as do driving an automobile or crossing an intersection. As different standards apply in the case of prescription drugs and over-the-counter drugs (the former requiring that the prescribing physician exercise the final judgment in each case), the risks must be balanced against the utility to the public-at-large. The warnings are directed to the prescribing physician who must make that balancing judgment in light of his personal knowledge of the patient's medical history.

Leibowitz v. Ortho Pharm. Corp.,307 A.2d 449, 457 (Pa. Super. 1973).

In July of 2005, Effexor's labeling contained more than two (2) pages of suicide related warnings including an FDA mandated pediatric "black box" warning[3] entitled "**Suicidality in Children and Adolescents**", as well as a modified version of the "Clinical Worsening and Suicide Risk" warning that, as it had since April of 2004, applied to adult and pediatric patients.[4] Wyeth CSUF ¶¶ 56, 57 & 58. Under the "Clinical Worsening and Suicide Risk" of the "Warnings" section, the Effexor XR label in use in July 2005 stated, in relevant part:

> Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the

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[3] A "black box" warning is the strongest warning that the U.S. Food and Drug Administration requires. Black-box warnings reveal "[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury" and "ordinarily must be based on clinical data." 21 C.F.R. § 201.57(c)(1).

[4] Dr. Rasefske acknowledged that the Effexor warning in effect in July of 2005 was contained in the 59th edition of the Physician's Desk Reference Guide, which he would have read prior to prescribing Effexor for Aaron. Wyeth Ex. 10, Deposition of Rasefske, p. 74.

> emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. . . .
>
> **Adults with MDD or co-morbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases**. . . .
>
> **Families and caregivers of pediatric patients being treated with antidepressants for [MDD] or other indications, both psychiatric and nonpsychiatric, should be alerted to the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. . .** Families and caregivers of adults being treated for depression should be similarly advised.

Wyeth CSUF ¶ 57 (bold in original). The plain language of the warning appears to advise physicians of the specific risk at issue in the instance case.

Plaintiff contends, however, that the warning was inadequate to inform Dr. Rasefske that adults were at risk for potential suicidal ideation. Generally, the adequacy of a warning in prescription drug cases must be proven by expert testimony. *See Demmler v. SmithKline Beecham Corp.*, 671 A.2d at 1154; *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 751 (E.D. Pa. 2007). In support, therefore, Plaintiff offers the report of his medical expert, Joseph Glenmullen, M.D. ("Dr. Glenmullen"). Wyeth argues that because Dr. Glenmullen offers an unsworn expert report, it is not competent for consideration at a motion for summary judgment. Moreover, Wyeth contends such report is particularly inappropriate in this instance because, despite several requests, Plaintiff failed to produce Dr. Glenmullen for deposition.

Rule 56 of the Federal Rules of Civil Procedure controls the materials that a district court may consider in ruling on a motion for summary judgment. Such material to be considered include "the pleadings, depositions, answers to interrogatories, and admissions on file, together

with the affidavits . . ." FED. R. CIV. P. 56(c). In describing the submission at issue here, Plaintiff indicated that Dr. Glenmullen submitted "a report in the form of an affidavit." Plaintiff's Brief in Opposition, p. 5. After having reviewed the entire document, however, it is clear to the Court that the substance of Dr. Glenmullen's report was not confirmed by either his oath or affirmation. The report of Plaintiff's expert fails to comply with Rule 56(e)[5]. It is an unsworn statement not competent for consideration on a motion for summary judgment. *See, e.g., Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158 n. 17 (1970) (unsworn statement does not meet the requirements of Fed. R. Civ. P. 56(e)). *See also Fowle v. C & C Cola*, 868 F.2d 59, 67 (3d Cir. 1989).

Plaintiff also argues that the label in effect at the time Dr. Rasefske prescribed the Effexor was inadequate to warn him of the risks to adult patients. Dr. Rasefske testified that it was his recollection that the Effexor suicide-related warnings addressed only pediatric and adolescent patients, and not adult patients. Wyeth CSUF ¶ 26. Even after having reviewed the warnings in effect in 2005 during his deposition, Dr. Rasefske testified that he did not remember "taking away the impression that it was adults. . . I remember [] I just formed an impression that the risk was in pediatric and adolescent patients." Wyeth Ex. 10, Deposition of Rasefske, pp. 76-77.

Notwithstanding Dr. Rasefske's contention that he believed the information set forth in the 2005 Effexor warning and the Physician's Desk Reference did not pertain to adults, and that there was no "causal role established" for enhanced risk of suicide in adults, Dr. Rasefske admitted he:

1. was aware of the suicide-related risks faced by depressed patients, and that such patients are at substantial risk of self-harm or suicide, Wyeth CSUF ¶ 20;

2. knew that depressed patients may have emerging suicidal ideation and behavior, whether or not they were taking antidepressants, Wyeth CSUF ¶ 21;

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[5] Despite Wyeth having raised this issue in its brief in support of summary judgment, Plaintiff has done nothing to correct the error, and in fact has ignored the issue entirely in his brief filed in opposition to Wyeth's motion for summary judgment.

3. was aware that patients treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of drug therapy, Wyeth CSUF ¶ 22;

4. knew that patients and their family should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, and other symptoms after beginning medication, Wyeth CSUF ¶ 23; and

5. Regularly treated depressed patients with modern antidepressants and did his best to keep abreast of the risks and benefits. Wyeth CSUF ¶ 25.

Dr. Rasefske had more than adequate information regarding the risks regarding depressed patients and antidepressants.

Dr, Rasefske's alleged incorrect belief that the 2005 Effexor warnings did not pertain to adults is of no moment. It is the duty of the prescribing physician to be fully aware of the characteristics of the drug he is prescribing and to advise the patient of any dangers or side effects associated with the use of the drug. *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d at 378. The evidence of record shows that Dr. Rasefske read the appropriate literature regarding Effexor, and was therefore warned of the relevant risks. It must also be noted that before prescribing the Effexor for Aaron, Dr. Rasefske did not consult with Aaron's regular physician, schedule an appointment for Aaron in order to evaluate him and/or discuss Effexor's risks and benefits, or speak with Dr. Perry.

Based on the above, the Court finds that the warning in effect in July of 2005, advised physicians of the specific risks at issue in the instance case, and there is no evidence that Wyeth breached its duty to exercise reasonable care to inform Dr. Rasefske and others similarly situated of the risks associated with prescribing antidepressants. Dr. Rasefske does not recall the specific warning he read, but admits he was aware of the risk for suicide in depressed patients taking antidepressants based upon his training and experience. Under the "learned intermediary" doctrine a physician can use the information obtained from the manufacturer, as well as his independent medical knowledge, in deciding whether or not to prescribe a certain drug. It has been long held in Pennsylvania that:

> It is for the prescribing physician to use his own independent

> medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.

Leibowitz v. Ortho Pharmaceutical Corp., 307 A.2d at 457. Dr. Rafeske testified that he was aware of the possible side affects of antidepressants and that he read the appropriate warnings either in Wyeth's insert or the Physician's Desk Reference Guide prior to prescribing Effexor for Aaron. Accordingly, Plaintiff is unable to show that Wyeth's Effexor warnings were inadequate, and his negligent failure to warn claim fails under the learned intermediary doctrine, and is unnecessary to address the proximate cause issue[6].

Because the Court finds that Wyeth was not negligent in the death of Aaron, Plaintiff's claims under Pennsylvania's Wrongful Death and Survival statutes must be dismissed.

C. Design Defect and Warranty Claims

In his brief in opposition to Wyeth's motion for summary judgment, Plaintiff makes no argument in support of either his design defect claim or his claims for breach of warranty. Notwithstanding this Court's assumption that Plaintiff has abandoned these claims, the Court finds that such claims substantively fail and must be dismissed.

To prevail in any negligence action, a plaintiff "must show that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage." *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003). Moreover, the determination of whether a product was negligently designed turns on whether "an alternative, feasible, safer design would have lessened or

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[6] To prevail on a negligent failure to warn claim, in addition to showing a failure to give an adequate warning, a plaintiff must also show a reasonable connection between such failure and the injury suffered. *Demmler v. SmithKline Beecham Corp.*, 671 A.2d at 1155. "In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Id.* (quoting *Mazur v. Merck & Co., Inc.*, 964 F.2d at 262.).

eliminated the injury plaintiff suffered." *Berrier v. Simplicity Mfg.*, 563 F.3d 38, 64 (3d Cir. 2009)(quoting *Habecker v. Clark Equipment Co.*, 36 F.3d 278, 281 (3d Cir. 1994)). Plaintiff failed to provide any record evidence that there was an alternate, feasible, safer design for Effexor that would have prevented Aaron's suicide. Wyeth's motion for summary judgment with regard to Plaintiff's negligent design claim shall be granted.

As set forth above, since the Pennsylvania Supreme Court's ruling in *Hahn v. Richter*, Pennsylvania courts, as well as federal courts applying Pennsylvania law, have consistently held that negligence is the only theory upon which a prescription drug manufacturer can be held liable for failure to warn. *See Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 547 (E.D. Pa. 2006); *Kline v. Pfizer, Inc.*, 2008 U.S. Dist. LEXIS 101655 (E.D. Pa. Oct. 31, 2008); *Lineberger v. Wyeth*, 894 A.2d 141, 145 (Pa. Super. 2006). Because *Hahn* requires that this Court dismiss all claims that do not rest on a theory of negligence, Plaintiff's express and implied warranty claims shall be dismissed.

V. CONCLUSION

Based on the foregoing, the motion for summary judgment filed by Defendant, Wyeth, shall be granted. An appropriate order follows.

s/ David Stewart Cercone
David Stewart Cercone
United States District Judge

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